

**REMARKS**

Claims 1- 6, 9 and 10 are pending in this application with claims 1, 3, 5 and 10 being amended and claim 2 being canceled by this response. Claims 1, 5 and 10 have been amended to include certain features of originally filed claim 2. Support for the amendments to claims 1, 5, 6 and 10 is found throughout the specification and originally filed claims, and more specifically, on page 7, lines 5 – 27 of the present specification. Thus, it is respectfully submitted that no new matter has been added by these amendments.

Additionally, Applicant would like to thank Examiner Ellis for the courtesy extended during the telephone conversation on August 11, 2008 as well as other telephone conversations which aided Applicant in preparing the response to the Final Office Action.

**Objection to the Specification under 35 USC 132(a)**

The Final Office Action asserts that amending the Specification to incorporate by reference information that was contained in a foreign patent application is improper. The Final Office action further asserts that any amendment must be accompanied by a statement that the amendment contains no new matter. Thus, Applicant's substitute specification is objected to because it is alleged that new matter was introduced and a certified English translation of the priority document is requested.

The present application derives its priority from Japanese Patent Application No. 2002-271730 filed on September 18, 2002 which defines the food or drink as including strictinin. A translation of Japanese Patent Application No 2002-271730 is submitted herewith and includes a statement that the translation is a true and accurate translation of the aforementioned Japanese Patent Application. Therefore, Applicant respectfully submits that the amendments to the Specification submitted with the response on March 19, 2008 do not include any new matter. Thus, Applicant requests that the Substitute Specification filed on March, 19, 2008 be entered.

**Rejection under 35 USC 112, first paragraph**

Claims 1 – 6, 9 and 10 are rejected under 35 USC 112, first paragraph as failing to comply with the written description requirement.

Specifically, the Final Rejection asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention because the originally filed specification did not include the term “strictinin”. As discussed in the response filed March 19, 2008, the claims were amended to correct an inadvertent typographical error in the specification by replacing the term “strychnine” with the correct term “strictinin”. Moreover, in view of the certified translation submitted herewith, it is clear that the Japanese Patent Application, from which this U.S. Nonprovisional application claims priority, includes support for a food and/or drink including strictinin. Specifically, the Japanese word “sutorekuchinin” contained in both the Japanese Application and subsequent PCT Application, both of which were authored in Japanese, was mistranslated. As shown in the attached translation, the correct translation of the term “sutorekuchinin” is “strictinin”. Therefore, it is respectfully submitted that the amendments to the claims made in the response date March 19, 2008 did not introduce new matter. Thus, it is further respectfully submitted that claims 1, 3 – 6, 9 and 10 comply with 35 USC 112, first paragraph. Consequently, withdrawal of the rejection is respectfully requested.

**Rejection under 35 USC 112, second paragraph**

Claims 1, 5 and 10 are rejected under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Final Rejection asserts that it is unclear is Applicant is still claiming one of the group or all the listed ingredients in the identified sections of the claims. Applicant has formally amended claims 1, 5 and 10 for purposes of clarity to recite that “the one or more ingredients selected from the group consisting of EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and strictinin”. Consequently, withdrawal of the rejection of claims 1, 5 and 10 is respectfully requested.

**Rejection of Claim 1 under 35 U.S.C. § 102(b)**

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Shokuhin Kenkyu Seika Jyohou (National Food Research Institute).

The present claimed invention provides a food/drink having antiallergenic action comprising one or more selected from the group consisting of epigallocatechin-3-O-(3-O-methyl)gallate (EGCG3"Me) and gallocatechin-3-O-(3-O-methyl)gallate (GCG3"Me) as an optical isomer thereof, epigallocatechin-4-O-(4-O-methyl)gallate (EGCG4"Me) and gallocatechin-4-O-(4-O-methyl)gallate (GCG4"Me) as an optical isomer thereof and strictinin, wherein one or more ingredients of EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and strictinin are contained in amount of 1mg to 500mg per one liter to daily intake of 3mg to 300mg and the one or more of EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and strictinin are obtained as a mixture containing tea extracts and ground tea wherein the tea is at least one selected from the group consisting of Benifuki, Benihomare and Benifuji. For the reasons presented below Shokuhin Kenkyu Seika Jyohou, hereinafter "Shokuhin", fails to disclose each feature claimed in amended claim 1.

Shokuhin discusses harvesting tea leaves at different times to obtain leaves with different levels of EGCG3"Me. While Shokuhin states that EGCG3"Me is an antiallergenic found in tea leaves, Shokunhin is merely concerned with identifying preferred times for picking the leaves and the preferred type of tea prepared from the leaves in order to increase EGCG3"Me content. This is fundamentally different from and not equivalent to the claimed composition which provides a "food/drink having an antiallergenic action...wherein one or more ingredients of EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and strictinin are contained in amount of 1mg to 500mg per one liter to daily intake of 3mg to 300mg and the one or more of EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and strictinin are **obtained as a mixture containing tea extracts and ground tea** is at least one selected from the group consisting of Benifuki, Benihomare and Benifuji". "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference" *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Additionally, "[t]he identical invention must be shown in as complete detail as is

contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Applicant respectfully submits that Shokuhin fails to meet the required burden and therefore does not anticipate the claimed composition. There is no enabling disclosure in Shokuhin of a range of EGCG3"Me that is useful in an antiallergenic food or drink. Moreover, there is nothing in Shokuhin that discloses or suggests that specified range of EGCG3"Me is **"obtained as a mixture containing tea extracts and ground tea"** as in the claimed composition. Shokuhin is not at all concerned with an amount of EGCG3"Me for use in a food or drink. Rather, Shokuhin seeks to maximize an amount of EGCG3"Me that may be present in particular tea leaves based on the time the leaf is picked.

The Rejection asserts that EGCG3"Me is inherently found in tea leaves of Benifuki or Seishin-Taipan as taught by Shokuhin. However, unlike Shokuhin, the claimed composition provides EGCG3"Me "contained in amount of 1mg to 500mg per one liter to daily intake of 3mg to 300mg" that is "obtained as a mixture containing tea extracts and ground tea" from any of "Benifuki, Benihomare and Benifuji". There is nothing in Shokuhin that discloses or suggests an equivalent composition. Shokuhin fails to disclose or suggest any composition of any type and instead focuses on harvesting tea leaves. Shokuhin merely describes maximizing EGCG3"Me content by picking the leaf at a certain time. Thus, Shokuhin is fundamentally different from the claimed composition which provides a food or drink having a specific range of EGCG3"Me content which allows the food or drink to be palatable to the user. As stated on page 7, lines 5 – 27 of the present Specification, Example 4 provides a comparison between two different types of solutions. The first solution is made solely from tea extracts and the second solution is "obtained as a mixture containing tea extracts and ground tea". The second solution having the extracts and the ground tea was preferred by seven of ten people because it was determined that the solution containing tea extracts and ground tea was "highly evaluated...as genuine tea". Thus, the claimed composition provides significant disclosure beyond the mere mention by Shokuhin of EGCG3"Me as an antiallergenic and identifying ideal harvesting times therefor. There is nothing in Shokuhin that discloses or suggests the claimed "food/drink having antiallergenic action" as claimed in claim 1. Therefore, as each feature of amended claim 1 is neither disclosed nor suggested by Shokuhin, Applicant respectfully submits that Shokuhin does not anticipate the

present claimed invention. Consequently, withdrawal of the rejection of claim 1 is respectfully requested.

Claims 5 and 10 are considered patentable for the reasons as presented above with respect to claim 1. Specifically, Shokuhin fails to provide enabling disclosure of the claimed composition and merely provides instructions regarding the harvesting time of tea leaves in order to maximize EGCG3"Me content. This is not equivalent to a "food/drink having antiallergenic action" that includes "one or more ingredients selected from the group consisting of EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and strictinin are **obtained as a mixture containing tea extracts and ground tea**, wherein the tea is at least one selected from the group consisting of Benifuki, Benihomare and Benifuji. Therefore, as each element of claims 5 and 10 are neither disclosed nor suggested by Shokuhin, Applicant respectfully submits the claims 5 and 10 are similarly not anticipated by Shokuhin.

In view of the above remarks and amendments to the claims, Applicant respectfully submits that claims 1, 5 and 10 are not anticipated by Shokuhin. As claims 3, 4 and 9 are dependent on claim 1 and claim 6 is dependent on claim 5, Applicant respectfully submits that claims 3, 4, 6 and 9 are similarly not anticipated by Shokuhin. Therefore, withdrawal of the rejection of claims 1 – 6, 9 and 10 is respectfully requested.

**Rejection of Claims 1 – 6, 9 and 10 under 35 U.S.C. § 103(a)**

Claim 1 – 6, 9 and 10 are rejected under 35 U.S.C. § 102(b) as being unpatentable in view of Yamamoto et al. (EP 1 157 693).

The present claimed invention provides a food/drink having antiallergenic action comprising one or more selected from the group consisting of epigallocatechin-3-O-(3-O-methyl)gallate (EGCG3"Me) and gallocatechin-3-O-(3-O-methyl)gallate (GCG3"Me) as an optical isomer thereof, epigallocatechin-4-O-(4-O-methyl)gallate (EGCG4"Me) and gallocatechin-4-O-(4-O-methyl)gallate (GCG4"Me) as an optical isomer thereof and strictinin, wherein one or more ingredients of EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and strictinin are contained in amount of 1mg to 500mg per one liter to daily intake of 3mg to 300mg

and the one or more of EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and strictinin are obtained as a mixture containing tea extracts and ground tea wherein the tea is at least one selected from the group consisting of Benifuki, Benihomare and Benifuji. For the reasons presented below, Yamamoto et al., fails to disclose or suggest each feature claimed in amended claim 1.

Yamamoto discusses the ability to combine EGCG3"Me as part of a food or beverage as a carrier. However, Yamamoto merely provides that a desired food or beverage is produced using tea extracts. This is wholly unlike the claimed composition which provides that the food/drink having antiallergenic affect includes EGCG3"Me that is "obtained from a mixture containing tea extracts and ground tea". The claimed composition provides for a highly effective antiallergenic composition that has a significant taste improvement over compositions such as those described in Yamamoto. Specifically, as shown in Example 4 on page 7 of the present specification, when comparing two types of product solutions, one made solely from tea extracts and a second "obtained as a mixture containing tea extracts and ground tea", the product made from the "mixture containing tea extracts and ground tea" is far superior in taste, color scent and flavor to the composition made solely using tea extracts. Specifically, seven out of ten persons that tasted the claimed composition indicated that it had a superior flavor and was similar to genuine tea and that it had a taste closer to tea made from genuine tea leaves.

Yamamoto is the author of both the present application as well as the cited reference and there is nothing in the cited European Patent that discloses or suggests a composition "obtained from a mixture containing tea extracts and ground tea". Rather, in paragraph 0024 of Yamamoto, relied on in the Rejection, states that the catechin derivative used in the Yamamoto composition "is in turn obtained by extracting tea leaves...with an aqueous solvent". This process is further shown in Figures 1 and 2 of Yamamoto. Thus, Yamamoto describes a composition made only from tea extracts that may be liquid or powder (paragraph 0030). However, this is unlike the claimed composition wherein the food/drink having antiallergenic action is "obtained from a mixture containing tea extracts and ground tea" which provides an enhanced flavor, taste and palatability, as compared to one formed only using tea extracts. Moreover, powdered tea extracts such as those described in Yamamoto are not equivalent to "ground tea" of the claimed

composition. Rather, and unlike “ground tea” powdered tea extracts such as those described in Yamamoto are formed using a spray drying or freeze-drying process which is known in the art. Therefore, as Yamamoto only uses tea extracts and not “a mixture containing tea extracts and ground tea”, Yamamoto neither discloses nor suggests the present claimed composition.

Claims 5 and 10 are considered patentable for the reasons presented above with respect to claim 1.

In view of the above remarks, Applicant respectfully submits that Yamamoto fails to disclose or suggest anything makes the invention as claimed in claim 1, 5 and 10 unpatentable. As claims 3, 4 and 9 are dependent on claim 1 and claim 6 is dependent on claim 5, it is respectfully submitted that these claims are patentable over Yamamoto. Consequently, withdrawal of the rejection of claims 1 – 6, 9 and 10 is respectfully requested.

**Rejection of Claims 1 – 6, 9 and 10 under 35 U.S.C. § 103(a)**

Claims 1 – 6, 9 and 10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Shokuhin Kenkyu Seika Jyohou (National Food Research Institute) in view of Yamamoto.

Applicant respectfully submits that the arguments presented above with respect to Shokuhin and Yamamoto, individually, are applicable and thus are incorporated herein by reference. Additionally, Shokuhin (with Yamamoto) fails to disclose or suggest the claimed food/drink having an antiallergenic action that is produced using a “mixture containing tea extracts and ground tea” as in the claimed composition. The Rejection further asserts that it would be obvious to modify Shokuhin with Yamamoto depending on desired application or on how strong the user prefers their tea. Applicant respectfully disagrees. Specifically, Shokuhin fails to discuss any acceptable amounts of EGCG3”Me for use in a composition of any type and certainly provides no enabling disclosure of a food or drink having an antiallergenic action that includes “one or more ingredients of EGCG3”Me, GCG3”Me, EGCG4”Me, GCG4”Me and strictinin are contained in amount of 1mg to 500mg per one liter to daily intake of 3mg to 300mg and the EGCG3”Me, GCG3”Me, EGCG4”Me, GCG4”Me and strictinin are obtained as a

mixture containing tea extracts and ground tea, wherein the tea is at least one selected from the group consisting of Benifuki, Benihomare and Benifuji” as recited in claim 1. Moreover, Shokukin neither discloses nor suggests producing a composition that is “obtained as a mixture containing tea extracts and ground tea”. Instead, Shokuhin merely describes obtaining tea at certain times when the concentration of EGCG3”Me is greatest. Thus, Shokuhin is fundamentally different from the claimed composition.

Yamamoto, similarly to Shokuhin, also describes an entirely different and non-equivalent process. Yamamoto describes using only tea extracts either in liquid or powder form to produce a food or beverage. Thus, Yamamoto (with Shokuhin) fails to disclose or suggest a food/drink having antiallergenic action that is “obtained as a mixture containing tea extracts and ground tea” as in the claimed composition. In fact, Yamamoto teaches away from the claimed composition because all compositions are described as being produced using only tea extracts. To modify the Yamamoto composition to be produced using “a mixture containing tea extracts and ground” as in the claimed composition would require undue experimentation that may result in the effectiveness of the Yamamoto composition being compromised. The use of a combination of ground tea and tea extracts to obtain the specified amount of the active ingredient as in the claimed composition is neither disclosed nor suggested by Yamamoto alone or in combination with Shokuhin.

Additionally, there is no reason to combine Shokuhin with Yamamoto because they each relate to entirely different processes which occur at different times during tea leaf processing. Shokuhin is concerned with harvesting at an ideal time to maximize EGCG3”Me content while Yamamoto is concerned with and describes a specific process for using a tea extract in liquid or powder form to produce a food or beverage. There is no reason to modify the tea extracting process described Yamamoto with the harvesting times discussed in Shokuhin. Moreover, even if one were to combine Shokuhin with Yamamoto, the resulting composition would merely produce a food or beverage from tea extracts that were extracted from leaves that were harvested at a time when the EGCG3”Me content was at a maximum level. There is nothing in Shokuhin and/or Yamamoto that discloses or suggests a food/drink including “one or more ingredients



selected from the group consisting of EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and strictinin are obtained as a mixture containing tea extracts and ground tea, wherein the tea is at least one selected from the group consisting of Benifuki, Benihomare and Benifuji" which produces a food/drink that has a superior, less astringent flavor that is rated closer to actual taste of genuine tea (see Example 4, present specification).

Claims 5 and 10 are considered patentable for the reasons presented above with respect to claim 1.

In view of the above remarks and amendments to the claims, Applicant respectfully submits that Shokuhin (with Yamamoto) fails to make the invention claimed in claims 1, 5 and 10 unpatentable. As claims 3, 4 and 9 are dependent on claim 1 and claim 6 is dependent on claim 5, it is respectfully submitted that claims 3, 4, 6 and 9 are also patentable over Shokuhin and/or Yamamoto. Consequently, withdrawal of the rejection of claims 1 – 6, 9 and 10 is respectfully requested.

#### **Nonstatutory Obviousness-type Double Patenting Rejection**

Claims 1 and 5 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 10 and 11 of US Patent No 6,638,524 (hereinafter "Tsuji").

The Rejection acknowledges that the claims of Tsujii are not identical to the present claims 1 and 5 but asserts that they are not patentably distinct from one another. Specifically, the Rejection asserts that Tsujii is drawn to a food/beverage that comprises strictinin in an amount of 5-100 mg/kg per day. However, claim 1 has been amended to recite that the "one or more ingredients selected from the group consisting of EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and strictinin are **obtained as a mixture containing tea extracts and ground tea**, wherein the tea is at least one selected from the group consisting of Benifuki, Benihomare and Benifuji". Unlike Tsujii, the claimed food or beverage is produced in a different manner from a

different set of ingredients. Tsujii is similar to Yamamoto discussed above in that the food/beverage described therein is produced using only tea extracts in various forms. Contrary to Tsujii, the claimed composition is "obtained as a mixture containing tea extracts and ground tea" which provides the active ingredient in the desired amount while providing a significant enhancement in taste, flavor and color such that the claimed composition is rated more highly and closer to genuine tea. Specifically, as discussed on page 7 of the Specification, Example 4 describes a testing process wherein 7 out of 10 people strongly preferred and more highly rated a composition formed from "a mixture containing tea extracts and ground tea". Thus, Tsujii teaches away from the claimed composition because it merely provides using tea extracts alone, which is rated less highly than the claimed composition that is "obtained as a mixture containing tea extracts and ground tea". Therefore, Applicant respectfully submits that amended claims 1 and 5 are patentable distinct from Tsujii. Consequently, withdrawal of the rejection of claims 1 and 5 is respectfully requested.

Having fully addressed the Examiner's rejections, it is believed that, in view of the preceding amendments and remarks, this application stands in condition for allowance. Accordingly then, reconsideration and allowance are respectfully solicited. If, however, the Examiner is of the opinion that such action cannot be taken, the Examiner is invited to contact the Applicant's attorney at the phone number below, so that a mutually convenient date and time for a telephonic interview may be scheduled.

Respectfully submitted,  
Hiroshi Nagai et al.

By: 

Jesse R. Bucholtz  
Reg. No. 55,027

Jack Schwartz & Associates, PLLC  
1350 Broadway, Suite 1510  
New York, New York 10018  
Tel. No. (212) 971-0416  
Fax No. (212) 971-0417  
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